

**REMARKS**

Claims 1-9, 11 and 13-31 were pending in the present application. Claims 1, 23, 29, and 31 have been amended herein, and claims 7-9 have been canceled herein without prejudice to their presentation in another application. Support for amended claim 1 can be found throughout the specification and original claims such as, for example, at page 15, lines 16 to 28, and page 16, lines 16 to 19 of the specification. Claims 23, 29, and 31 have amended herein solely to add a period at the end of the claim; thus, there is no change in claim scope. No new matter has been added. Upon entry of the present amendments, claims 1-6 and 28-31 will be pending, and claims 11 and 13-27 remain withdrawn.

**I. Objections**

The Office objects to the disclosure because it “contains an embedded hyperlink and/or other form of browser-executable code” (see, Action at page 3). The specification has been amended herein to delete all embedded hyperlinks and/or other forms of browser-executable codes. Applicants respectfully request that the objection be withdrawn in light of the amended specification.

The Office further objects to claims 29 and 31 for failing to end in a period. Claims 29 and 31 have been amended herein and now end in a period. Applicants respectfully request that the objection be withdrawn in light of the amended claims 29 and 31.

**II. The Claimed Invention is Novel**

Claims 1, 2, and 7 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by De Lemos-Chiarandini et al., J. Cell Biol., 1987, 104, 209-219 (hereinafter, the “De-Lemos reference”). Applicants traverse the rejection and respectfully request reconsideration thereof because the De-Lemos reference does not teach every element recited in the rejected claims.

A claim is anticipated under 35 U.S.C. §102 only if every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *See Verdegel Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). As a preliminary matter, claim 7 has been canceled herein, rendering its rejection moot. In regard to

claim 1, Applicants respectfully assert that the De-Lamos reference does not teach every element recited in claim 1. Specifically, Applicants are unable to locate any portion of the De-Lamos reference that reports a composition comprising a peptide antigen, wherein the peptide antigen is a heterologous peptide antigen. Thus, the De-Lamos reference does not teach every element of Applicants' claimed invention. Accordingly, Applicants respectfully assert that the claimed invention is novel and request that the rejection under 35 U.S.C. §102 be withdrawn.

### **III. The Claimed Invention is Not Indefinite**

Claims 1-7 and 28-31 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite, for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Office alleges that “in the recitation of ‘an externally disposed peptide antigen and a protein of the Major Histocompatibility Complex (MHC)’ in claim 1, it is allegedly unclear whether or not the limitation ‘externally disposed’ applies [to] the ‘protein of the MHC’” (see, Action at page 3). Although Applicants respectfully disagree and believe that pending claim 1 is sufficiently clear, solely to advance prosecution and without disclaimer of subject matter, claim 1 has been amended herein to recite, in relevant part, “wherein said peptide antigen and said protein of the MHC are externally disposed.” In light of the amendments made herein, Applicants respectfully assert that claim 1 is even more clear, and request that the claim rejection be withdrawn.

### **IV. The Claimed Invention is Enabled**

Claims 1-7 and 28-31 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the enablement requirement. Specifically, the Office alleges that the amount of guidance provided in the instant specification is not seen as sufficient to enable one of skill in the art to produce a vaccine “which has a prophylactic or therapeutic effect, because it is unpredictable whether the claimed composition is usable as a prophylactically or therapeutically effective adjuvant” (see, Action at pages 4-5). Applicants traverse the rejection and respectfully request reconsideration thereof because one skilled in the art would not be required to perform undue experimentation to make and use the claimed invention.

As a preliminary matter, the Office mistakenly asserts that Applicants' vaccine composition "must possess the properties of a prophylactically or therapeutically effective adjuvant" (see, Action at page 4; emphasis in original). There is absolutely no requirement that Applicants' vaccine composition act as or possess properties of an "adjuvant." Indeed, an adjuvant is, generally, an optional component of a vaccine composition (such as Alum, Freund's adjuvant, etc.) that enhances the immune response generated by the vaccine composition. The vaccine composition elicits an immune response to the peptide antigen contained therein. Thus, the claimed vaccine composition need not have any "adjuvant" effect. Accordingly, the Office's premise is not accurate. Thus, the Office has not carried its burden under 35 U.S.C. §112, first paragraph. In light of the foregoing discussion, Applicants respectfully assert that the claimed invention is enabled, and request that the claim rejection be withdrawn.

**V. The Claimed Invention is Supported by Ample Written Description**

Claims 1 and 4 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Office alleges that "the skilled artisan cannot envision all the contemplated co-stimulatory molecules encompassed by the instant claims" (see, Action at page 5). Applicants traverse the rejection and respectfully request reconsideration thereof.

As a preliminary matter, Applicants note that claim 1 does not recite a "costimulatory molecule."

In regard to claim 4, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence of reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). Applicants' specification identifies numerous co-stimulatory molecules including, for example, B7 and IL-2 (see, pages 23 and 24 of the specification). Other co-stimulatory molecules are identified in the specification including, for example, other cytokines and interferons (i.e., IL-15, IL-6, GM-CSF, IFN $\gamma$ ) (see, pages 23 and 24 of the specification). Thus, Applicants respectfully assert that one skilled in the

art armed with Applicants' disclosure, would appreciate that Applicants were in possession of the genus of co-stimulatory molecules at the time of their invention. Indeed, even the Examiner asserts, when referring to the Greenwald reference, that one of skill in the art at the time the invention was made "was aware of the existence of numerous structurally and functionally diverse costimulatory molecules" (see, Action at page 5).

The Action mistakenly concludes that "the skilled artisan cannot envision **all** the contemplated costimulatory molecules encompassed by the instant claims" (see, Action at page 5; emphasis added). There is no requirement, however, that one skilled in the art be able to envision "all" possible costimulatory molecules in order to be in possession of the genus of costimulatory molecules.

Accordingly, Applicants respectfully assert that the claimed invention is supported by ample written description, and request that the claim rejection be withdrawn.

## **VI. Conclusion**

Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicants' undersigned representative at (610) 640-7851 to resolve any remaining issues.

Respectfully submitted,

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